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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,902	01/11/2001	Roberts S. David	PC9047D	1327

23913 7590 07/10/2003

PFIZER INC  
150 EAST 42ND STREET  
5TH FLOOR - STOP 49  
NEW YORK, NY 10017-5612

EXAMINER
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SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/10/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/758,902

Applicant(s)

DAVID ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                            |                                                                             |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> | 6) <input type="checkbox"/> Other: _____                                    |

***DETAILED ACTION***

1. Applicants' amendments and response received June 18, 2002, paper 9 is acknowledged. Claim 18 was amended.
2. Currently claims 18-19 are pending and under consideration.

***Prior Citations of Title 35 Sections***

3. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

***Prior Citations of References***

4. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or 1449 have been submitted with this office action.

***Information Disclosure Statement***

5. The Examiner acknowledges receipt of copies of missing references. These references are now considered by the examiner. See attached copy of revised PTO 1449.

***Rejections Withdrawn***

6. Rejection of claims 18-19 under 35 U.S.C. 112, second paragraph, made in paragraph 4 of the office action mailed 12/14/2001, paper # 4 is withdrawn in view of applicants' amendments.

***Rejections Maintained***

7. Rejection of claims 18-19 under 35 U.S.C. 103, made in paragraph 5 of the office action mailed 12/14/2001, paper # 4 is maintained.

The rejection was as following:

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (The veterinary record, May 2, 1987) and Geresi et al. (Ann. Immuno. Hung Vol. 25, pp. 37-40 1985) in view of Wu et al. (The Journal of Immunology, Vol. 148, pp. 1519-1525, 1992) and Gluck et al. (US Patent 5,879,685).

Claims are drawn to a multicomponent clostridial vaccine composition comprising a viral antigen and a saponin adjuvant.

Green et al. teach the formulation of a multivalent clostridial vaccine in analogous art (see page 435) for the purpose of stimulating a protective immune response against multiple strains and species of this pathogen. Green et al. teach multicomponent clostridial vaccines such as Covexin 8, Hepatavac and Tasvax (see table 1). Green et al. teach the inclusion of six or more clostridial immunogens such as toxoids from *Cl. chauvoei*, *Cl. septicum*, *Cl. tetani*, *Cl. nvyoi*, *Cl. haemolyticum* and *Cl. perfringins* (type B, C and D) for the realized reduced threat of loss of livestock, wherein the use of six or more of clostridial immunogens would have provided for a broader range of immune response against clostridial pathogens and increase the likelihood of protection against infection by a broader range of species or strains of clostridium. Green et al. teach aluminum hydroxide as the adjuvant (page 438, column 1). Green et al. do not teach viral antigen.

Geresi et al. teach the formulation of multivalent clostridial vaccine compositions, which also comprise a viral immunogen (see page 38). The reference differs from the instantly claimed invention by failing to show the use of saponin as an adjuvant.

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Wu et al. show the use of saponin adjuvant in association with an antigen, wherein the exemplified vaccine comprised a viral antigen (see abstract and results in page 1521 and discussion in page 1523). Wu et al. teach that vaccine formulations containing the saponin adjuvant produced significantly higher titers of antibody than alum absorbed vaccines. Wu et al. do not teach a respiratory virus.

Gluck et al. teach an immunostimulating combination of influenza virus and *Clostridium tetani* (see abstract and claims 6-9).

Therefore, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify or combine the compositions of Green et al. and Geresi et al., include a respiratory virus taught by Gluck et al. and to include the saponin adjuvant of Wu et al. because all of the references are directed to the formulation of vaccines for the attainment of enhance immune response. One with ordinary skill in art would have been motivated to combine these compositions because Green et al and Geresi et al. both teach the formulation of multicomponent clostridial vaccines, Gluck et al. and Geresi et al. teach the inclusion of viral antigens in bacterial vaccine composition and Wu et al. teach the use of saponin as an adjuvant which provides for an enhanced immune response when in association with either a clostridial antigen or a viral antigen, respectively. In the absence of unexpected results, Green et al. and Geresi et al., in view of Gluck et al. and Wu et al. obviate the instantly claimed invention.

Applicants' arguments filed 6/18/2002 have been fully considered but they are not persuasive.

Applicants argue that cited art does not provide any suggestion or motivation to make the claimed invention. Applicants further argue that suggestion to carry out the claimed invention must be found in the cited art, not in applicants' disclosure. Applicants further argue "In fact, the only suggestion to combine the separate elements of the cited references on this record is the examiner's own view and the application of hindsight in the reconstruction of the art."

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation of combining immunogenic compositions containing *Clostridium* species and respiratory virus is coming from teachings of Gluck et al. Gluck et al. teach an immunostimulating combination of influenza virus and *Clostridium tetani* (see abstract and claims 6-9). Use of different adjuvants such as saponin is well known in the art of vaccine preparation and saponin adjuvant has been commercially available (i.e Quil A) (see Wu et al. page 1519 right column).

In response to applicants' argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

***Conclusion***

8. No claim is allowed.

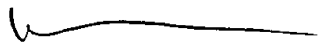
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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July 4, 2003

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER